**NIH POLICY MANUAL**

# 54516 - REVIEW OF INSTITUTIONAL NATIONAL RESEARCH SERVICE AWARD APPLICATIONS

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## A. Purpose

This chapter explains NIH policy, procedures, and responsibilities for the initial review of Institutional National Research Service Award (NRSA) applications (T32). Understanding and implementing these policies, procedures, and responsibilities will enhance and promote fair and uniform procedures within NIH.

## B. Applicability

These policies are applicable to the review of all new, competing continuation and supplemental Institutional National Research Service Award applications.

## C. Background

An Institutional National Research Service Award (NRSA) is a grant to a public or nonprofit private institution to enable the institution to select and make National Research Service Awards to promising students and provide them with predoctoral and/or postdoctoral research training in those scientific areas relevant to the mission of the particular BID. An Institutional NRSA is awarded to support a long-term training program focused on a particular objective or central theme. The proposed training should be in areas which encompass concepts and methods of the relevant biological, behavioral, or biomedical disciplines, including basic and clinical sciences, and be of sufficient depth to enable the trainees, upon completion of the program, to formulate research projects and pursue careers as investigators. The support of Institutional NRSAs is expected to ensure that highly trained scientists will be available in adequate numbers and in appropriate areas and fields for the nation's biological, behavioral, and biomedical research needs.

## D. References

1. Section 487, PHS Act (42 U.S.C.288).

2. Code of Federal Regulations Title 42, Part 52h, Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects.

3. Code of Federal Regulations Title 42, Part 66, National Research Service Awards.

4. NIH Manual Chapter 1805 - Use of Advisors in Program and Project Review and Management.

5. NIH Manual Chapter 4107 - Review of Applications and Award of Grants Involving Human Subjects.

6. NIH Manual Chapter 4110 - Request for Applications (RFAs) and Program Announcements (PAs).

7. NIH Manual Chapter 4206 - Responsibility for Care and Use of Animals.

8. NIH Manual Chapter 4510 - Referral and Initial Review of NIH Grant and Cooperative Agreement Applications.

9. NIH Manual Chapter 4511 - Project Site Visits Involving Review of Grant and Cooperative Agreement Applications.

10. NIH Manual Chapter 4512 - Summary Statements.

11. NIH Manual Chapter 4513 - Review of NIH Programs and Grant and Cooperative Agreement Applications by National Advisory Councils and Boards.

12. NIH Manual Chapter 4514 - Role of Staff at Advisory Committee Meeting and Exchange of Information Between Initial Review Groups and Bureaus, Institutes, and Divisions.

13. NIH Manual Chapter 4517 - Review of Program Project Grant Applications.

14. NIH Manual Chapter 4810 - National Research Service Awards

## E. Definitions

**1. Administrative Note** - A note in the summary statement related to aspects other than scientific/technical merit. It is required in summary statements for Institutional NRSAs to address recruitment and participation of minority groups and may be used to call attention to other matters.

**2. Program Director** - The institutional official dean/director responsible for the overall direction of the training program, including the selection and appointment of trainees.

**3. Predoctoral Trainee** - An individual who has received a baccalaureate degree and is currently either (1) training in a program that leads to the award of the doctor of philosophy in science (or equivalent degree), or (2) engaged in full-time research training while also interrupting studies for a professional degree (e.g., M.D.S., D.O. and similar degree).

**4. Postdoctoral Trainee** - An individual who has received a Ph.D., M.D., D.D.S., D.O., D.V.M., Sc.D., Eng.D., Dr.P.H., D.N.S., O.D., D.P.M., or equivalent degree, and demonstrates a clear interest in a research career.

**5. Faculty** - The group of preceptors, supervisors, mentors, or sponsors that provides the supervised research experience in a field, discipline, or specialty of biological, biomedical or behavioral research.

## F. Policy

The NIH is committed to objective, high-quality peer review of grant applications submitted by the scientific community and to the principle of funding on a competitive and equitable basis.

To maintain an objective review process separate from programmatic considerations and to avoid real or apparent conflicts of interest, NIH review staff are organizationally independent from the program units and have responsibility for, and autonomy in, the conduct of review activities.

Institutional NRSA applications are assigned by DRG to the relevant BID for initial review by a chartered BID initial review group (IRG),or, as arranged with DRG, by a BID ad hoc group.

During initial review group meetings and site visits, discussions of BID policy concerning current paylines and fundable priority scores, as well as evaluative comments, may bias review; therefore, such discussions must be avoided by NIH staff throughout the review process.

The membership of the initial review group should reflect a balance in terms of experience, expertise, and specialty so as to ensure peer review of all elements of an application. For NRSA applications, reviewers should have substantial experience in graduate research training, with an active interest in the methods and planning of research training in their discipline, field, or specialty, and a record of accomplishment in training predoctoral and/or postdoctoral students.

To be eligible for an award, a minimum of two (2) predoctoral and/or post-doctoral trainee positions must be recommended for approval by the IRG.

## G. Responsibilities

1. The Deputy Director for Extramural Research and Training, NIH, has responsibility for the continuing evaluation of the overall soundness and objectivity of the entire NIH initial review process. This responsibility, shared with the Director, DRG, includes the right to send observers to site visits and meetings of BID initial review groups, including those evaluating NRSA applications.

2. BIDs have responsibility for ensuring the quality and objectivity of the evaluation of applications assigned to them for initial review.

3. BID review staff members have responsibility for managing the initial review of designated applications, including the selection of reviewers, management of site visits and documentation of IRG recommendations.

## H. Conflict of Interest

As general policy, to avoid real or apparent conflicts of interest, advisors are disqualified from reviewing applications where their participation might have an effect on the interest of individuals or organizations with which the advisors are closely related or affiliated. Specific guidance is provided in Manual Chapters 1805 and 2300-735-2. Reviewers and NIH staff alike must be well informed about these policies.

Executive Secretaries are normally disqualified from managing the review of applications from members of their respective committees. The chairpersons of disqualified committees may not chair the review of those applications. (See NIH Manual Chapter 1805 F.2.c.)

Concerning conflicts of interest in NRSA applications, the relationships among potential reviewers and the program director, faculty, and trainees and candidates must be carefully considered.

## I. Distinguishing Features of an Institutional National Research Service Award

1. The Institutional NRSA provides support to institutions possessing the necessary faculty, resources, and facilities to develop enhance research training opportunities in relevant biological, behavioral, and biomedical research areas. These programs should demonstrate a strong commitment to the career development of minorities by their past record and future plans for recruitment of minorities underrepresented in the biomedical sciences.

2. The Institutional NRSA may be in a broadly defined fundamental discipline or specialized area of research rather than on a specific topic of research. However, the proposed areas of research and the training faculty must

demonstrate interrelationships which provide evidence of a cohesive and synergistic research training environment.

3. The Institutional NRSA may support predoctoral research training leading to the award of a Ph.D. (or equivalent degree) in certain specialized fields, but it cannot be used to support study leading to a professional doctoral degree, such as the M.D., D.O., D.D.S. or D.V.M.

4. The program director must have recognized scientific and administrative leadership, as well as experience in research training. He/she is responsible for the selection and appointment of trainees and for the overall direction of the program. The participating faculty included in the program should be capable of providing research experience and research support for the trainees.

## J. Review Criteria

Factors to be considered in the review of NRSA applications include:

- **Training Program:**

  1. The specific areas in which research training is available in participating laboratories, their relevance to the overall goals of the training program, and the breadth and depth of training.

  2.The adequacy of the overall organization of the program, the factors involved in assigning trainees to specific laboratories, and the overall plan for monitoring trainee performance.

  3. The appropriateness of the curriculum, such as degree requirements, didactic courses, laboratory experiences, and qualifying examinations in meeting the proposed goal of the training program.

  4. The availability and quality of other training activities, such as seminars, conferences, journal clubs, and visiting lecturer series.

- **Program Direction:**

  1. The Program Director's scientific background, quality of research, experience in research training, and ability to provide the necessary leadership.

  2. The advisory structure and administration of the program.

- **Training Faculty:**

  1. The quality of the training faculty, as evidenced by, for example, current research grant support and publication record, and the faculty's research activities, scientific accomplishments, and experience in basic and/or clinical research training.

  2. The extent to which preceptors are available to plan and supervise the research experience of trainees.

  3. Evidence of cooperation and collaboration among faculty.

- **Trainees:**

  1. The plan for recruiting and selecting trainees.

  2. The adequacy of the applicant pool (quantitative and qualitative).

  3. The qualifications of trainees and their appropriateness for the proposed program.

- **Training Environment:**

  1. The adequacy of the facilities and resources available for training experiences, i.e., available space and equipment and clinical, animal, or other resources.

  2. The adequacy of the intellectual environment in which the training program is being conducted.

  3. Integration of interdisciplinary components and interaction among faculty and among trainees.

  4. The extent of institutional support for the program.

  5. Sources of support for students affiliated with the program.

- **Training Record of the Faculty and Program:**

  1. Number of individuals trained.

  2. Their present positions, i.e., whether in biomedical research positions.

3. Their research activities subsequent to training.

4. The ability of the program to commit all trainee positions to qualified candidates.

5. The attrition record of trainees.

6. Publication record of past and present trainees.

- **Programs Emphasizing Research Training for Physicians:**

  These programs are intended to attract and train appropriate numbers of individuals with the M.D., D.D.S., and D.V.M. degrees to become competent and dedicated investigators. Additional factors to be considered in the review of these programs include:

  1. Two years of intensively supervised research training in clinical or basic science are recommended as a minimum requirement to provide the necessary foundation for the development of a competitive research career. (Part of this research experience may be acquired with other than NRSA support.)

  2. The training program must provide evidence of a close relationship with scientists in clinical and/or basic science departments.

  3. The training program should make only a minimal demand upon the trainee for service activities; routine clinical duties must be limited to 20 percent or less of the trainee's time.

  4. Research training programs from clinical departments should show appointments of at least as many postdoctoral MDs as Ph.D.s. during a project period.

  5. Evidence of continued research activities of trainees is a major positive factor in the renewal of any research training grant application.

- **Human Subjects, Animals and Environment:**

  The protection of human subjects, the welfare of animals, and biohazard issues are covered in NIH Manual chapters 4107, 4206, and 4510.

## K. Other Considerations

NIH policy is to promote broader and systematic efforts to recruit individuals from minority groups currently underrepresented in biomedical and behavioral research. Initial review groups will address the following points:

### 1. Minority Recruitment

The applicant's specific plans for the recruitment of individuals from underrepresented groups.

### 2. Minority Training Record

The applicant's past record in selecting underrepresented minorities and in training them for research positions.

National Research Service Award (NRSA) programs are intended to attract and train individuals to pursue independent careers as investigators. Accomplishments of NRSA programs in these areas with respect to minority groups will ensure that they are progressively better represented in biomedical and behavioral research.

## L. Implementation

The details of the pre-application phase, assignment to an IRG, and the preparation for the review of an NRSA application are indented to be fully consistent with the corresponding sections in NIH Manual Chapter 4517, Review of Program Project Grant Applications.

### 1. Site Visits

A site visit is not a prerequisite for evaluating an NRSA application. Site visits should be made only if the additional information needed by the IRG to evaluate the application cannot be obtained by letter or telephone call.

While there is no inherent need that these applications be site visited prior to the IRG meeting, a decision to make a site visit is a review responsibility, is generally made by the Executive Secretary, and is based on considerations which may include the following:

a. an application from an institution whose experience in research training is not extensive or well known;

b. issues or concerns in applications which can be clarified for the IRG with the benefit of information obtained during a site visit, e.g., concerns about faculty or departmental interactions

and collaborations, multiple applications from the same department, qualifications and abilities of participating faculty, or quality of training.

**2. Selection of the Site Visit Team or Special Review Committee**

Guidelines are intended to be consistent with NIH Manual Chapter 4511 and 4517. These Manual Chapters detail the purpose of the site visit, the responsibilities of the Executive Secretary, the resources available to the Executive Secretary, and contacts with the Program Director, reviewers, and extramural staff regarding site visit arrangements. The size and composition of each site visit team are determined by the particular details of the application to be reviewed; it is the responsibility of the Executive Secretary to make these determinations based on a thorough review of the application and, as needed, on suggestions from program staff. The number of site visitors generally ranges from two to five, and the site visit team should reflect a balance in terms of experience and expertise so as to provide proper peer review of the training program. Site visitors should be recognized investigators in the relevant scientific disciplines and, most importantly, have experience in training students in those scientific areas. The chairperson, usually a member of the IRG, should be experienced in the review of training grant applications and knowledgeable in the general scientific area of the training program and have leadership qualities.

**3. The Site Visit**

Details concerning the pre- and post-site visit meetings and the site visit report are found in NIH Manual Chapter 4517.

The focus during a site visit should be on those training elements requiring clarification and on information that is new or updated since submission of the application. The applicant should be reminded that the site visitors have studied the application in detail and that any repetition of its contents must be brief and concise. Current trainees should be available for interview; this interview should be conducted with only the executive secretary, trainees, and site visit team present.

Although the site visit focuses on meeting the requirements of the visitors for collecting information, of no less importance is the applicant's impression of the site visit. The applicant should feel that adequate opportunity has been provided to make an effective presentation. In this regard, site visitors should refrain from asking questions or making statements which might be construed as recommendations or statements of opinion.

**4. The Chartered Review Committee**

The functioning of the IRG is described in NIH Manual Chapters 4510 and 4517. After thorough discussion of the application and consideration of the review criteria (see Section J), a recommendation is made generally for approval or disapproval, and a priority rating assigned to applications recommended for approval. Other considerations such as the budget and recruitment and training of minorities are then discussed. The Executive Secretary is responsible for preparation of the summary statement.

If, however, the Review Committee votes to defer an application for additional information, a further recommendation for a site visit may be made for such reasons as:

a. wide divergence among the reviewers as to the merits of the application and an inability to resolve the divergence of opinion without additional information obtainable by site visit;

b. uncertainty about the organization of the program which may be substantively clarified with a site visit;

c. uncertainty about the potential for training or the qualities or availability of trainees;

d. changes relevant to the proposed program which may have come about since the application was submitted.

**5. The Ad Hoc Initial Review Group**

When a review is done by an ad hoc IRG, the review group may visit the applicant institution to consider the application, gather additional information, make a recommendation for approval, disapproval, or deferral, and, in the case of approval recommendations, assign a priority score. A written report is prepared on site, and from this the Executive Secretary prepares the summary statement which is forwarded directly to the Advisory Council.

**6. The Summary Statement**

The summary statement for an Institutional National Research Service Award application should present the review findings and recommendations in a uniform manner. The format prescribed in Manual Chapter 4512, Summary Statements, should be followed.

An administrative note is required for IRG comments about the applicant's plan for recruiting and selecting minority trainees and about the current status of minority individuals who have trained under the program.

## M. Additional Information

For further information on this manual chapter, contact the Extramural Programs Management Officer, OERT, Shannon Building, Room 314, telephone 496-2241.

## N. Additional Copies of this NIH Manual Chapter

For extra copies of this chapter, send a Form NIH 414-5 "Request for Manual Chapter," to the Printing and Reproduction Branch, DTS, in Bldg. 31, Room B3BE07.